Remarks

Claims 116, 124-131, 139-144, 153, 160, 161, 170-177, 182 and 183 are presently pending in the subject application. Claims 131, 139-144, 153, 160, 161 and 170-174 are withdrawn from further consideration as being directed to a non-elected invention.

Reconsideration and allowance in view of the above amendments and the following remarks are respectfully requested.

Claims 117-119, 132-134, 145-152, 154-159, 162-169 and 178-181 are canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application.

Claims 116, 124, 125, 139, 140, 161, 170, 171 and 175-177 have been amended herein to recite the sequence of the target binding portion or the probe as opposed to the sequences to which they bind. Amended claims 116, 124 and 125 incorporate limitations of canceled claims 119, 176 and 177, respectively; amended claims 139 and 140 incorporate limitations of canceled claims 178 and 179, respectively; amended claims 161, 170 and 171 incorporate limitations of canceled claims 165, 180 and 181, respectively; amended claim 175 incorporates limitations of claim 169; and amended claims 176 and 177 incorporate limitations of claims 124 and 125, respectively. The language of claims 116, 124, 125, 139, 140, 161, 170, 171 and 175-177 is further supported in the specification at, for example, page 5, lines 3-8, and page 19, lines 18-27.

Claim 153 has been amended herein to recite first and second amplification oligonucleotides having the limitations of the amplification oligonucleotides of canceled claim 159. Claim 153 has been further amended to indicate that the target region of the SARS-CoV nucleic acid, if present in the test sample, is amplified under isothermal amplification conditions. Support for this amendment can be found in the specification at, for example, page 26, line 7 *et seq.*

Claim 173 has been amended herein to emphasize that the target binding portion forms a hybrid with the target sequence under the isothermal amplification conditions of the exposing step of claim 161. Support for this amendment can be found in the specification at, for example, page 29, line 13 *et seq.* and in Example 1.

Claims 182 and 183 are new and depend from claims 153 and 161, respectively. New claims 182 and 183 recite that the target region of the SARS-CoV nucleic acid is amplified by a transcription-based amplification. Support new claims 182 and 183 can be found in the specification at, for example, page 18, lines 17-22, and the paragraph bridging pages 18 and 19.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 116-119, 124-130, 176 and 177 stand rejected by the Examiner under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants submit that this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is hereby respectfully requested.

Rejection Under 35 U.S.C. § 103

Claims 116-119, 124-130, 145 and 175-181 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over GenBank Accession No. NC_004718.1 in view of Peiris *et al.* (U.S. Patent Application Publication No. US 2005-0009009 A1). GenBank Accession No. NC_004718.1 is cited for disclosing the complete genomic sequence of the SARS coronavirus, and Peiris is cited for teaching the use of oligonucleotides in a diagnostic assay for detecting SARS. Applicants respectfully traverse this rejection for the reasons that follow.

The probes of the claimed invention are limited to probes having a target binding portion that consists of or is contained within and includes at least 18 contiguous bases of the base sequence of SEQ ID NO:3, its complement, or a DNA equivalent of one of these sequences. Examples 1 and 2 of the instant application illustrate two probes having sequences which meet the limitations of the claimed probes. The first is a probe having self-hybridizing end portions and a target hybridizing region that shares 18 contiguous bases in common with SEQ ID NO:3 that was detected in real-time in a transcription-based amplification. The second is a linear probe that shares 21 contiguous bases in common with SEQ ID NO:3 and was used in an end-point, transcription-based amplification and

detected in a Hybridization Protection Assay (HPA). As noted in Example 1, probes having the sequences of SEQ ID Nos. 44 and 45 did not detectably hybridize to SARS-CoV derived amplicon. From SEQ ID NO:23 on page 8 of the specification, it can been seen that the target hybridizing regions of SEQ ID Nos. 44 and 45 overlap five of the 5'-end most nucleotides and six of the 3'-end most nucleotides of SEQ ID NO:3, respectively. The differences in performance between these various probes was unpredictable and, thus, it was unpredictable that the claimed probes would perform optimally in detecting SARS-CoV derived nucleic acid in a test sample.

The amplification claims have been amended herein to recite that the test sample is exposed to isothermal conditions during the exposing step, such that the target region of SARS-CoV nucleic acid is amplified without appreciably altering the temperature of the test sample. This is significant, because unlike thermal cycling reactions, the amplification oligonucleotides of an isothermal reaction have a greater tendency to form primer-dimers and to self-hybridize and, therefore, regions for amplifying targeted nucleic acids must be demonstrated empirically. Applicants have identified optimal regions for amplifying SARS-CoV nucleic acid that are not predictable, including regions containing at least 18 contiguous bases of SEQ ID Nos. 24 and 25. As shown in Example 1 of the instant application, 100 copy sensitivity can be achieved with amplification oligonucleotides of the claimed invention.

Claims 146-152 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over GenBank Accession No. NC_004718.1 in view of Peiris *et al.* (U.S. Patent Application Publication No. US 2005-0009009 A1) as applied to claims 116-119, 124-130, 145 and 175-181 above and further in view of McDonough *et al.* (U.S. Patent No. 5,766,849). McDonough is being cited for teaching oligonucleotides complementary to a target sequence where the 5' region complexes with a promoter for an RNA polymerase. Applicants submit that McDonough does not overcome the deficiencies of GenBank Accession No. NC_004718.1 and Peiris noted above. Accordingly, withdrawal of this rejection is hereby respectfully requested.

Conclusion

Applicants submit that the subject application is in condition for allowance and, accordingly, early notice to that effect is respectfully requested.

Please charge the fee due for a one-month extension of time, and any other fee which may be due, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Respectfully submitted,

Date: March 6, 2008

By: /Charles B. Cappellari/
Charles B. Cappellari
Registration No. 40,937
Attorney for Applicants

GEN-PROBE INCORPORATED
Patent Department/Mail Stop #1
10210 Genetic Center Drive
San Diego, CA 92121
PH: 858-410-8927
FAX: 858-410-8928